

## Timeline of FDA Health Claims and Soyfoods

YEAR	EVENT
1990	<p>Nutrition Labeling and Education Act directs the FDA to issue regulations for authorized health claims on foods and supplements.</p> <p>There must be significant scientific agreement among qualified experts that the claim is supported by the totality of publicly available scientific evidence.</p>
1999	<p>FDA establishes an authorized health claim that soy protein lowers cholesterol, therefore reducing risk of heart disease.</p> <p>This is the first and only authorized health claim for a single food; others are for nutrients or other food compounds (eg, sodium, fiber) or food groups such as fruits and vegetables.</p>
2003	<p>FDA announces new qualified health claims.</p> <p>These claims don't require the rigid, significant scientific agreement of authorized health claims.</p>
2007	<p>FDA quietly announces establishing procedures to remove certain authorized health claims.</p> <p>This is announced in the <i>Federal Register</i> but doesn't draw widespread interest.</p>
2008	<p>Antisoy group The Weston A. Price Foundation (WAPF) files a citizen petition challenging the soy protein claim.</p> <p>The FDA doesn't respond to the petition, despite the rules mandating a response.</p>
2014	<p>The WAPF sues the FDA for not responding to the petition.</p> <p>The FDA is required to either approve or deny a citizen petition within 180 days (150 days as of 2012) or provide a tentative response indicating why it's unable to reach a decision.</p>
Jan 2016	<p>FDA rejects the WAPF petition. FDA says that the studies submitted don't represent scientific consensus. It also rejects the claim that soy is unsafe.</p> <p>FDA also cites the 2007 <i>Federal Register</i> note about introducing a procedure to downgrade authorized health claims.</p>
Oct 2017	<p>FDA announces a proposal to revoke the soy protein authorized health claim and opens a comment period.</p> <p>FDA says there's still evidence that soy protein reduces risk of heart disease; it's likely the claim will be downgraded to qualified. This would be the first revoked authorized health claim.</p>
Jan 2018	<p>The original comment period ends.</p> <p>The Soy Nutrition Institute requests an extension to the comment period; the FDA grants 60 additional days.</p>
March 2018	<p>The comment period extension ends.</p> <p>There's no official date for when the FDA will announce a decision regarding the status of the claim.</p>